Response

In the specification, the paragraph at page 9, lines 16-10, has been amended to correct a typographical error.

Claims 1, 3, 5-18, 24-29, 31, and 47 are pending.

Claims 1, 4, 19-21, 23, and 30 have been canceled.

Claims 1, 3, 5-7, 11, 18, 24-29, 31, and 47 have been amended.

No new matter has been added with the amendments. The scope of the claims is intended to be the same after the amendment as it was before the amendment.

Objections to the Specification

The Examiner objected to the specification at page 9, line 10, with regard to the recitation of a dose of 50 U/kg being equivalent to 500 ng/kg or *0.5 mg/kg*, which the Examiner states should read as "0.5 μg/kg."

The specification has been amended as suggested by the Examiner. Accordingly, withdrawal of this objection is respectfully requested.

Rejection of Claims under 35 USC § 112(2)

The Examiner rejected Claim 47 under Section 112(2) for the use of indefinite claim language.

Claim 47 (and others) have been amended as suggested by the Examiner to recite a patient "in need thereof."

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims under 35 USC § 112(1)

The Examiner rejected Claims 25-26 under Section 112(1) as nonenabled. The Examiner maintains that the specification fails to provide an enabling disclosure for the subject matter recited in the claims.

The Examiner stated as follows (emphasis added):

> The claims are drawn to **the prevention of myocardial ischemia** by administering EPO...

The Examiner is in error. Claims 25-26 recite a method of preventing or reducing *an ischemic injury associated with* myocardial ischemia. Examples of *ischemic injury* are provided throughout the specification.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejection of Claims under 35 USC §§ 102(e)/103 (Brines)

The Examiner rejected Claims 1-21, 23-31, and 47 under Section 102(e) as anticipated by Brines (USP 6,531,121). At page 8, the Examiner rejected Claims 3-5, 17, 19-23, 29 [sic]-26, 28 and 30 under Section 102(e) as anticipated by, or under Section 103(a) as obvious over Brines. This rejection is respectfully traversed.

The Examiner maintains that Brines teaches each of the elements recited in the claims. However, at page 8, the Examiner stated as follows (emphasis added):

> ...Brines et al., however, do not explicitly teach a specific the exact range that spans the length of the time of administration of EPO (e.g., continuous administration for 1-35; claim 3) and the time in which the desired EPO blood levels are achieved (claims 4, 24, 26, 28, 30 and 47).

It is noted that the claims have been amended to more clearly recite the subject matter claimed – which amendments have been taken from Claims 3 and 4:

- the administration of EPO as a *single treatment*
- given *at a defined time* of:
  - about *1-35 minutes prior to* the ischemic event,
  - *during* the ischemic event,
  - at *commencement* of a reperfusion,
  - *during* a reperfusion,
- such that a blood concentration of *about 0.5-10 U/ml* is achieved
- *within about 1-35 minutes* following administration of the EPO.

Brines does *not* teach or suggest Applicant's methods as recited in the claims.

Brines teaches administering several doses of EPO – one dose at *24 hours before* an event, and *a second dose* at just before the event.

This is pointed out by the Examiner in the Office Action at page 6, lines 7-10, with reference to Example 3 (emphasis added):

> Brines et al. teach of method of protecting the myocardium from ischemic injury by administering 5000 U/kg erythropoietin (EPO) ***24 hours prior and again immediately before*** an induced ischemic event to the heart...

The Examiner also acknowledges that Brines further teaches that serum levels are achieved – *at the earliest* – at *1 hour* post-administration, citing to Brines at col. 12, lines 19-39 (Office Action at pages 6-7, bridging paragraph):

> When the invention is practiced by systemic administration, Brines' et al. teach the following concentrations of EPO to be administered....and finally, the time in which to expect the EPO blood/serum concentration to be achieved.
>
> > In a preferred embodiment...Such serum levels may be achieved at about 1, 2, 3, 4, 5, 6, 7, 8, 9, or 10 hours post-administration (column 12, lines 19-39).

The Examiner repeats this at pages 7-8, bridging sentence:

> ...This EPO serum concentration level is *achieved in about 1-10 hours* when systemic administration is used (parenterally)...

Applicant has unexpectedly found that an effective EPO blood serum level of about 0.5-10 U/ml can be achieved within 1-35 minutes following administration of EPO to a patient – by administering the EPO as a *single treatment – by timing the delivery – not* at *24 hours* prior to an event as in Brine's teachings – but rather *and significantly* at *1-35 minutes prior* to an ischemic event, or *during* the ischemic event, or *at the commencement* of a reperfusion, or *during* a reperfusion.

Nor is it inherent in Brines' method that a blood concentration of *about 0.5-10 U/ml* is achieved *within about 1-35 minutes* following administration of the EPO. The Examiner – in fact – acknowledges that Brines teaches that the serum levels are achieved at 1-10 *hours* post-administration. See above for the Examiner's statements in the Office Action at pages 6-7, (bridging sentence), and at pages 7-8 (bridging sentence).

The Examiner has failed to make a *prima facie* case of obviousness based on the cited reference. Accordingly, withdrawal of this rejection is requested.

With regard to the Examiner statements at pages 10-12 as to the limitations of certain of the claims, Applicant states as follows.

Claim 6. The Examiner's interpretation of the phrase "100 times the normal level" in Claim 6 is correct as being an EPO level of about 100-5000 mU/ml, as stated in the specification at pages 9-10.

Claims 12-16. These claims depend from Claim 1, which is neither taught nor suggested by Brines' disclosure.

Claims 25, 27. The Examiner's statement regarding Claims 25 and 27 is *incorrect*. Those claims are not to a method of *reducing myocardial ischemia* in a patient, as stated by the Examiner at page 11, but to a method of preventing or reducing *an ischemic injury associated with* myocardial ischemia. Furthermore, for the reasons stated above, Brines does not teach or suggest Applicant's methods as recited in either of Claims 25 or 27.

Claims 17, 19-21, 23. Claims 19-23 have been canceled. Claim 17 (indirectly) depends from Claim 1, which, as discussed above, is neither taught nor suggested by Brines.

Brines does not teach or suggest Applicant's methods as claimed. Accordingly, withdrawal of this rejection is requested.

Extension of Term. The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that Applicant has inadvertently overlooked the need for a petition for extension of time. If any extension and/or fee are required, please charge Account No. 23-2053.

It is submitted that the present claims are in condition for allowance, and notification to that effect is respectfully requested.

Respectfully submitted,

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